

ROBBINS GELLER RUDMAN  
& DOWD LLP  
SHAWN A. WILLIAMS (213113)  
Post Montgomery Center  
One Montgomery Street, Suite 1800  
San Francisco, CA 94104  
Telephone: 415/288-4545  
415/288-4534 (fax)  
shawnw@rgrdlaw.com  
– and –  
DARREN J. ROBBINS (168593)  
DAVID C. WALTON (167268)  
CATHERINE J. KOWALEWSKI (216665)  
655 West Broadway, Suite 1900  
San Diego, CA 92101-3301  
Telephone: 619/231-1058  
619/231-7423 (fax)  
darrenr@rgrdlaw.com  
davew@rgrdlaw.com  
katek@rgrdlaw.com

Attorneys for Plaintiff

[Additional counsel appear on signature page.]

UNITED STATES DISTRICT COURT  
NORTHERN DISTRICT OF CALIFORNIA

DENIS MULLIGAN, Individually and on	)	No.
Behalf of All Others Similarly Situated,	)	
	)	<u>CLASS ACTION</u>
Plaintiff,	)	
	)	COMPLAINT FOR VIOLATION OF THE
vs.	)	FEDERAL SECURITIES LAWS
	)	
IMPAX LABORATORIES, INC., LARRY	)	
HSU, ARTHUR A. KOCH and BRYAN M.	)	
REASONS,	)	
	)	
Defendants.	)	
	)	<u>DEMAND FOR JURY TRIAL</u>

## INTRODUCTION

1  
2       1.       This is a securities class action on behalf of all persons who purchased or otherwise  
3 acquired the common stock of Impax Laboratories, Inc. (“Impax” or the “Company”) between June  
4 6, 2011 and March 4, 2013, inclusive (the “Class Period”), against Impax and certain of its former  
5 and/or current officers and/or directors for violations of the Securities Exchange Act of 1934 (the  
6 “1934 Act”). These claims are asserted against Impax and certain of its officers and/or directors who  
7 made materially false and misleading statements during the Class Period in press releases, analyst  
8 conference calls, and filings with the SEC.  
9

10       2.       Impax is a specialty pharmaceutical company engaged in the development,  
11 manufacture and marketing of bio-equivalent pharmaceutical products, referred to as generics, in  
12 addition to the development of branded products.  
13

14       3.       Specifically, throughout the Class Period, defendants violated the federal securities  
15 laws by disseminating false and misleading statements to the investing public in connection with  
16 manufacturing deficiencies at the Company’s Hayward, California manufacturing facility, including  
17 the impact the deficiencies would have on the Company’s ability to gain U.S. Food and Drug  
18 Administration (“FDA”) approval for RYTARY™ (“Rytary”), an extended-release drug for  
19 treatment of Parkinson’s disease. As a result of defendants’ false statements, Impax’s stock traded at  
20 artificially inflated prices during the Class Period, reaching a high of \$27.02 per share on October 2,  
21 2012.  
22

23       4.       On March 4, 2013, Impax announced that the FDA had completed an inspection of  
24 the Company’s Hayward facility. The FDA’s inspection covered three areas. First, it covered a  
25 re-inspection of the Hayward facility, in connection with a warning letter the FDA issued in May  
26 2011, to verify the implementation of corrective actions by the Company. Second, it covered a Pre-  
27 Approval Inspection for Rytary, as analytical method validation and a portion of the stability data  
28

1 was generated at the Hayward facility. And third, it covered a general good manufacturing practices  
2 inspection. Based on its inspection, the FDA issued a new Form 483 (a form used by the FDA to  
3 document and communicate deficiencies in a company's quality system discovered during an on-site  
4 inspection), as it had found twelve "observations," or problems, at the Hayward facility that the  
5 Company needed to correct, including three repeat manufacturing problems that had not been  
6 corrected since prior inspections. The Company further indicated that due to the manufacturing  
7 deficiencies, it did not expect to be able to launch Rytary or a generic version of Concerta, a drug for  
8 the treatment of attention deficit hyperactivity disorder, until 2014.

10 5. Concurrently, on March 4, 2013, Impax filed a Form 8-K with the SEC providing a  
11 redacted version of the Form 483.

12 6. On this news, Impax's stock plummeted \$5.20 per share to close at \$14.80 per share  
13 on March 5, 2013, a one-day decline of 26% on high volume.

14 7. The true facts, which were known by the defendants but concealed from the investing  
15 public during the Class Period, were as follows:

16 (a) The Company failed to maintain proper quality control and manufacturing  
17 practices at its Hayward facility in violation of current Good Manufacturing Practices ("cGMP").

18 (b) The Company failed to take proper remedial actions to correct quality control  
19 issues previously identified by the FDA in prior inspections at the Hayward facility.

20 (c) The extent of the adverse impact the manufacturing deficiencies at the  
21 Hayward facility could have on the Company's ability to successfully launch its new drug, Rytary.

22 (d) Based upon the above, defendants lacked a reasonable basis for their positive  
23 statements about the Company and its outlook, including statements about its ability to launch  
24 Rytary or generic Concerta in 2013.  
25  
26  
27  
28



1           14. Defendant Impax is a specialty pharmaceutical company engaged in the development,  
2 manufacture and marketing of bio-equivalent pharmaceutical products in addition to the  
3 development of branded products.

4           15. Defendant Larry Hsu (“Hsu”) is, and at all relevant times was, the Company’s Chief  
5 Executive Officer (“CEO”), President and a director.

6           16. Defendant Arthur A. Koch (“Koch”) was, at relevant times and until his resignation  
7 on June 29, 2012, Chief Financial Officer (“CFO”) and Executive Vice President, Finance of the  
8 Company.  
9

10           17. Defendant Bryan M. Reasons (“Reasons”) is, and has been since June 2012, the  
11 Company’s CFO and Senior Vice President, Finance.

12           18. The defendants named above in ¶¶15-17 are referred to herein as the “Individual  
13 Defendants.”  
14

15           19. The Individual Defendants, because of their positions with the Company, possessed  
16 the power and authority to control the contents of Impax’s quarterly reports, press releases and  
17 presentations to securities analysts, money and portfolio managers and institutional investors, *i.e.*,  
18 the market. They were provided with copies of the Company’s reports and press releases alleged  
19 herein to be misleading prior to or shortly after their issuance and had the ability and opportunity to  
20 prevent their issuance or cause them to be corrected. Because of their positions with the Company,  
21 and their access to material non-public information available to them but not to the public, the  
22 Individual Defendants knew that the adverse facts specified herein had not been disclosed to and  
23 were being concealed from the public and that the positive representations being made were then  
24 materially false and misleading. The Individual Defendants are liable for the false statements  
25 pleaded herein.  
26  
27  
28

**FRAUDULENT SCHEME AND COURSE OF BUSINESS**

20. Defendants are liable for: (i) making false statements; or (ii) failing to disclose adverse facts known to them about Impax. Defendants' fraudulent scheme and course of business that operated as a fraud or deceit on purchasers of Impax common stock was a success, as it: (i) deceived the investing public regarding Impax's prospects and business; (ii) artificially inflated the price of Impax common stock; and (iii) caused plaintiff and other members of the Class to purchase Impax common stock at inflated prices.

**BACKGROUND**

21. Impax, a speciality pharmaceutical company, engages in the development, manufacture, and marketing of bioequivalent pharmaceutical products. The Company operates in two divisions, Global Pharmaceuticals and Impax Pharmaceuticals. The Global Pharmaceuticals division develops, manufactures, sells, and distributes generic pharmaceutical products. This division provides its generic pharmaceutical prescription products directly to wholesalers and retail drug chains, and generic pharmaceutical over-the-counter and prescription products through unrelated third-party pharmaceutical entities, in addition to offering research and development services. The Impax Pharmaceutical division develops proprietary brand pharmaceutical products for the treatment of central nervous system disorders, including epilepsy, migraine, multiple sclerosis, Parkinson's disease, and restless leg syndrome, and promotes third-party branded pharmaceutical products. Impax markets and sells its generic pharmaceutical prescription drug products in the continental United States and the Commonwealth of Puerto Rico.

22. Impax has historically focused on generic drugs, which offer notably lower margins than branded drugs. In 2008, the Company launched its branded products division in an effort to diversify its revenue base. Rytary, also known as IPX066, is the first drug that Impax sought to take through the entire FDA approval process for new drugs.

1           23.     Impax has two manufacturing facilities, one in Hayward, California, where the  
2 Company is based, and one in Taiwan. The Company conducts most of its research and  
3 development activities at its Hayward facility.

4           24.     The FDA and Impax have been at odds over the Company's Hayward facility since at  
5 least 2010. On June 3, 2011, Impax received a warning letter from the FDA, dated May 31, 2011,  
6 related to an inspection the FDA conducted of its Hayward facility between December 13, 2010 and  
7 January 21, 2011 ("May 2011 warning letter"). The warning letter cited problems in deviation from  
8 cGMP. CGMPs for human pharmaceuticals are regulations enforced by the FDA and govern  
9 manufacturing processes, stability testing, record keeping and quality standards. The May 2011  
10 warning letter cited problems in Impax's sampling and testing of in-process materials and drug  
11 production, its production record review and its process for investigating the failure of certain  
12 manufacturing batches to meet specifications.  
13

14           25.     During the first quarter of 2012, the FDA conducted a re-investigation of the  
15 Hayward facility in connection with the May 2011 warning letter and a general GMP inspection. In  
16 connection with the GMP inspection, the FDA issued a Form 483 in May 2012. A Form 483  
17 "Notice of Inspectional Observations" is a form used by the FDA to document and communicate  
18 deficiencies in a company's quality system discovered during an on-site inspection. According to  
19 the FDA, a satisfactory re-inspection of the Hayward facility would be required in order to close out  
20 the issues raised in the May 2011 warning letter.  
21

22  
23                   **DEFENDANTS' FALSE AND MISLEADING STATEMENTS**  
24                   **ISSUED DURING THE CLASS PERIOD**

25           26.     On June 6, 2011, Impax issued a press release providing an update on the FDA site  
26 inspection of the Hayward facility and its receipt of a warning letter. The release stated in part:

27                   Impax Laboratories, Inc. today announced that late Friday, June 3, it received a  
28 warning letter from the U.S. Food and Drug Administration (FDA) dated May 31,  
2011 related to an on-site inspection of its Hayward, Calif. manufacturing facility  
conducted between December 13, 2010 and January 21, 2011.

1 In the warning letter, the FDA cited deviations from current Good  
 2 Manufacturing Practice (cGMP) for Finished Pharmaceuticals. The deviations cited  
 3 related to sampling and testing of in process materials and drug products, production  
 4 record review and our process for investigating the failure of certain manufacturing  
 5 batches (or portions of batches) to meet specifications. As a result of the FDA's  
 6 initial inspection results, the Company conducted a voluntary recall in March of 2011  
 7 of five lots of Fenofibrate capsules 200 mg at the wholesale level and took additional  
 8 remedial actions as noted below.

9 The Company notes that the observations cited in the letter relate to the  
 10 Hayward manufacturing facility only, and do not relate to any of the Company's  
 11 other facilities. It also notes that until remedial action is complete and the FDA has  
 12 confirmed compliance with cGMP, approval of pending and new applications listing  
 13 the Hayward facility as a manufacturing location of finished dosage forms may be  
 14 withheld. The warning letter did not place restrictions on the Company's ability to  
 15 manufacture and ship product. ***While during the past three months, the production  
 level at the Hayward facility was reduced to implement several key changes in the  
 Company's quality system, the Company is now producing product at a normal  
 pace and does not currently plan to reduce its product manufacturing or hold  
 shipments of finished product.***

16 Following the initial inspection, the Company took a number of steps to  
 17 thoroughly review its manufacturing systems and standards, including the use of  
 18 leading consulting firms to assist in that review. ***This work is ongoing and the  
 Company is committed to improving its manufacturing practices.*** The Company  
 19 will continue to work to fully address the FDA's concerns and to resolve these  
 20 issues. The Company will respond to the FDA's warning letter within the mandated  
 21 15 business day response period.

22 "Impax remains committed to providing the highest quality products to our  
 23 customers and working with the FDA to diligently resolve any issues," said Larry  
 24 Hsu, Ph.D., president and CEO, Impax Laboratories. ***We intend to promptly  
 respond to the FDA's letter, and have already begun to implement changes and  
 establish procedures that address the observations cited during the inspection. We  
 will work diligently to remedy any outstanding issues in a timely manner.***

25 Dr. Hsu concluded, ***We don't anticipate that this manufacturing setback  
 will delay our ongoing research and development activities. We expect to continue  
 to develop our generic pipeline of 82 products and two brand products.***

26 27. On June 16, 2011, Impax filed a Form 8-K with the SEC, which stated in part:

27 On June 15, 2011, Charles V. Hildenbrand, Senior Vice President,  
 28 Operations, informed Impax Laboratories, Inc. (the "Company") of his intent to  
 resign effective June 17, 2011. The Company is currently aggressively seeking a new  
 executive with experience in pharmaceutical manufacturing and operations. On an  
 interim basis, Mr. Hildenbrand's responsibilities will be assumed by the Chief  
 Executive Officer of the Company.

28 28. Subsequently, on June 21, 2011, Impax issued a press release announcing that it had  
 hired two executives to improve quality control and manufacturing processes. The release stated in  
 part:



1 Impax Laboratories, Inc. today announced two executive appointments that will  
 2 strengthen the company's leadership in the critical areas of operations and quality  
 3 affairs. The company has appointed Mark Fitch as Senior Vice President Global  
 4 Operations and Jeff Nornhold as Senior Vice President Global Quality Affairs. Both  
 5 Mr. Fitch and Mr. Nornhold will report to Impax's President and Chief Executive  
 6 Officer, Larry Hsu, Ph.D.

7 \* \* \*

8 Mr. Nornhold, who has 20 years of pharmaceutical industry experience, joins  
 9 Impax from Watson Pharmaceuticals, Inc., where he was most recently Vice  
 10 President, Quality Operations - International, and was responsible for outside of the  
 11 U.S. manufacturing sites for both dosage and active pharmaceutical ingredients.  
 12 While at Watson, he also served as Vice President U.S. Quality Operations leading  
 13 the development and execution of quality initiatives for all U.S. sites. Prior to joining  
 14 Watson in 2000, he held numerous leadership positions within the pharmaceuticals  
 15 industry. He earned a Bachelor of Science degree in chemistry from Bowling Green  
 16 State University and a Master's in Business Administration from the University of  
 17 Southern California Marshall School of Business.

18 "We are very pleased that Mark and Jeff have joined Impax to oversee these  
 19 two very critical areas of our business," said Larry Hsu, Ph.D., president and CEO of  
 20 Impax. ***"They are accomplished executives with a strong track record and extensive  
 21 pharmaceutical and business leadership experience. We have experienced  
 22 significant growth the past several years and their addition further enhances our  
 23 management team."***

24 29. On August 2, 2011, Impax issued a press release announcing its second quarter 2011  
 25 financial results. The Company reported net income of \$12.6 million, or \$0.19 diluted earnings per  
 26 share ("EPS"), for the second quarter of 2011. The release stated in part:

27 "Our second quarter 2011 revenues and earnings were lower than the prior  
 28 year period primarily due to higher second quarter 2010 sales from the remaining  
 29 exclusive period of generic Flomax(R). However, our second quarter 2011 revenues  
 30 improved sequentially over the first quarter 2011 revenues and exceeded our  
 31 expectations," said Larry Hsu, Ph.D., president and CEO, Impax Laboratories, Inc.  
 32 "The sequential improvement was primarily due to the late April receipt of our  
 33 supplier's initial product shipment from 2011 quota of generic Adderall XR(R)  
 34 which resulted in second quarter generic Adderall XR(R) product sales of \$58.2  
 35 million, as compared to \$36.1 million in the first quarter of 2011."

36 \* \* \*

37 Dr. Hsu further stated, "We are working expeditiously to resolve the  
 38 manufacturing observations raised in the warning letter to the satisfaction of the U.S.  
 39 Food and Drug Administration (FDA). In late June 2011, we submitted our warning  
 40 letter response and will continue to cooperate with the FDA to resolve the  
 41 observations. ***We have already made significant manufacturing and quality control  
 42 systems improvements and believe we have addressed a number of the FDA's  
 43 observations. Upon our internal completion, we will request a re-inspection of our  
 44 Hayward facility by the FDA, the timing of which is wholly dependent upon the  
 45 FDA's availability. Based on our most recent estimate, we expect to incur charges***

1 *of approximately \$10.0 million in 2011 related to the development and*  
 2 *implementation of manufacturing and quality control systems improvements*  
 3 *associated with our response to the observations raised in the warning letter."*

4 *"This current interruption has not impacted our ability to execute our long-*  
 5 *term growth strategy.* We have a significant pipeline of generic products pending at  
 6 the FDA and continue to file Abbreviated New Drug Applications which we believe  
 7 will create additional product launch opportunities. Regarding our brand business, we  
 8 remain on schedule to file a New Drug Application for IPX066, our leading brand  
 9 product candidate for Parkinson's Disease, in the fourth quarter of 2011. We also  
 10 remain active pursuing external opportunities with the potential to further drive  
 11 future growth," concluded Dr. Hsu.

12 30. On August 4, 2011, Impax filed with the SEC its Form 10-Q for its second quarter  
 13 ended June 30, 2011, which included the same results previously reported in the Company's August  
 14 2, 2011 press release. The Form 10-Q stated in part:

15 In June 2011, we received a warning letter from the U.S. Food and Drug  
 16 Administration (FDA) related to an on-site FDA inspection of our Hayward,  
 17 California manufacturing facility conducted between December 13, 2010 and  
 18 January 21, 2011. In the warning letter, the FDA cited deviations from current Good  
 19 Manufacturing Practices (cGMP), which are extensive regulations governing  
 20 manufacturing processes, stability testing, record keeping and quality standards. In  
 21 summary, the FDA observations related to sampling and testing of in-process  
 22 materials and drug products, production record review, and our process for  
 23 investigating the failure of certain manufacturing batches (or portions of batches) to  
 24 meet specifications. The FDA observations do not place restrictions on our ability to  
 25 manufacture and ship our products. The warning letter is available on the FDA's  
 26 website at [www.fda.gov](http://www.fda.gov).

27 We have taken a number of steps to thoroughly review our quality control  
 28 and manufacturing systems and standards and are working with several third-party  
 experts to assist us with our review. *This work is ongoing and we are committed to*  
*improving our quality control and manufacturing practices. In late June 2011, we*  
*filed our response with the FDA and will continue to cooperate with the FDA to*  
*resolve the FDA observations. We have made significant quality improvements and*  
*are working to complete the material elements of our internal work as quickly as*  
*possible. Upon the completion of our internal work, we will request a FDA re-*  
*inspection of our Hayward, California manufacturing facility, with the goal of*  
*being able to close out the observations to FDA's satisfaction by the early part of*  
*first quarter 2012.*

31. On November 1, 2011, Impax issued a press release announcing its third quarter 2011  
 financial results. The Company reported net income of \$20.0 million, or \$0.30 diluted EPS, for the  
 third quarter of 2011. The release stated in part:

*"During the third quarter, we continued to make significant quality*  
*improvements and are diligently working to resolve the manufacturing*  
*observations raised in the June warning letter. These efforts remain a top priority*

1 *throughout the Company. However, it has not distracted us from continuing to*  
 2 *focus on our business as evidenced by our profitable results in the third quarter or*  
 3 *hindered our investments in new product opportunities,”* said Larry Hsu, Ph.D.,  
 president and CEO, Impax Laboratories, Inc.

4 Dr. Hsu continued, “We have provided the U.S. Food and Drug  
 5 Administration (FDA) with updates on our progress with quality improvements and  
 6 established dialogue with the agency. We have implemented a global quality  
 7 improvement program with the assistance of our external consultants. Our focus  
 8 remains on working expeditiously to meet our internal goal of closing out the  
 9 warning letter by the end of February 2012, the timing of which is dependent upon  
 10 the FDA’s availability to re-inspect our Hayward facility.”

11 Dr. Hsu concluded, “Throughout this process we have continued to focus on  
 12 growth initiatives. Our generic pipeline of 47 products pending approval has never  
 13 been larger and continues to expand as we have already filed 10 new product  
 14 applications in 2011. Within our brand division, we remain on track to file a New  
 15 Drug Application for IPX066, our leading brand product candidate for Parkinson’s  
 16 Disease, by the end of this year. In addition, we continue to pursue internally  
 17 developed products and business development candidates that are consistent with our  
 18 stated objectives of high growth and high margin opportunities.”

19 32. On November 3, 2011, Impax filed with the SEC its Form 10-Q for its third quarter  
 20 ended September 30, 2011, which included the same results previously reported in the Company’s  
 21 November 1, 2011 press release. The Form 10-Q stated in part:

22 We have taken a number of steps to thoroughly review our quality control  
 23 and manufacturing systems and standards and are working with several third-party  
 24 experts to assist us with our review. This work is ongoing and we are committed to  
 25 improving our quality control and manufacturing practices. *In late June 2011, we*  
 26 *filed our response with the FDA and will continue to cooperate with the FDA to*  
 27 *resolve the FDA observations. We have made significant quality improvements and*  
 28 *are working to complete the material elements of our efforts as quickly as possible*  
*with the goal of being able to close out the warning letter by the end of February*  
*2012.*

33. On February 9, 2012, Impax issued a press release entitled “Impax Laboratories  
 Provides Update on Status of Warning Letter Resolution for its Hayward Facility,” which stated in  
 part:

Impax Laboratories, Inc. today provided an update on the status of its resolution of  
 the previously disclosed warning letter issued by the U.S. Food and Drug  
 Administration (FDA) covering its Hayward manufacturing facility. Late last year,  
 Impax received an acknowledgement letter from the FDA stating that it had received  
 a complete response from Impax to the warning letter. However, a satisfactory re-  
 inspection is required to close out the warning letter and the re-inspection by the  
 FDA has not occurred to date. Therefore, the Company’s previously stated goal for  
 completing the closing out of the warning letter before the end of February 2012 may  
 not occur. Until such re-inspection is completed and the warning letter is closed out,

1 approval of the Company's pending drug applications listing the Hayward  
2 manufacturing facility as a manufacturing location may be withheld by the FDA.

3 ***"We worked as quickly and diligently as possible to ensure we addressed all***  
4 ***FDA concerns, and look forward to a timely resolution," said Larry Hsu, Ph.D.,***  
5 ***president and CEO, Impax Laboratories. "At the same time, we have been***  
6 ***successfully executing our growth strategy, including pursuing external growth***  
7 ***opportunities, further advancing our generic and brand R&D pipeline, and***  
8 ***servicing our customers. Our focus on achieving these objectives is evident in***  
9 ***several recent positive events, including obtaining a long-term licensing agreement***  
10 ***for Zomig®, advancing our pipeline with the filing of a New Drug Application for***  
11 ***IPX066 and submitting 11 Abbreviated New Drug Applications in 2011."***

12 ***As part of its Global Quality Improvement Program, the Company said it***  
13 ***has revised its Standard Operating Procedures, made key staffing changes,***  
14 ***revalidated manufacturing processes, conducted additional training, and***  
15 ***purchased and validated new equipment.***

16 ***Hsu added, "Improving the operation of all of our production facilities and***  
17 ***company-wide quality systems has strengthened our Company, and continuous***  
18 ***improvement will remain a top priority. We appreciate the communication and***  
19 ***guidance provided by the FDA throughout this process and look forward to their re-***  
20 ***inspection of our Hayward facility."***

21 Yesterday Impax received notice from the FDA that it has forfeited  
22 exclusivity on its generic version of Doryx 150mg.

23 34. On February 28, 2012, Impax issued a press release announcing its fourth quarter and  
24 full year 2011 financial results. The Company reported net income of \$21.9 million, or \$0.33 diluted  
25 EPS, for the fourth quarter of 2011. Additionally, the Company reported net income of \$65.5  
26 million, or \$0.97 diluted EPS, for the full year 2011. The release stated in part:

27 Dr. Hsu concluded, ***"We are also excited about the prospects that our brand***  
28 ***business offers from both our research efforts and business development***  
29 ***initiatives. Our New Drug Application for IPX066 was accepted by the FDA and***  
30 ***the process to prepare for launch upon approval is well underway. In addition, our***  
31 ***License Agreement for Zomig® will contribute meaningfully to our 2012 and 2013***  
32 ***financial performance. We will continue to actively pursue generic and branded***  
33 ***internally developed products and business development candidates that offer long***  
34 ***term growth opportunities."***

35 35. On February 28, 2012, Impax filed with the SEC its Form 10-K for its fiscal year  
36 ended December 31, 2011, which included the same results previously reported in the Company's  
37 February 28, 2012 press release. The Form 10-K stated in part:

38 We have taken a number of steps to thoroughly review and remediate our  
39 quality and manufacturing systems and standards and are working with several third-  
40 party experts to assist us. ***This work is ongoing, and we have made significant***

1 ***quality improvements and are committed to improving our quality control and***  
 2 ***manufacturing practices.*** From late June 2011 through the end of 2011, we filed our  
 3 response and subsequent updates with the FDA and have continued to cooperate with  
 4 the FDA to resolve the FDA observations. In December 2011, we received an  
 5 acknowledgment letter from the FDA stating that it had received a complete response  
 6 from us to the warning letter.

7 36. On May 1, 2012, Impax issued a press release announcing its first quarter 2012  
 8 financial results. The Company reported net income of \$12.4 million, or \$0.18 diluted EPS, for the  
 9 first quarter of 2012. Additionally, the Company provided an update on the FDA's re-inspection of  
 10 its Hayward manufacturing facility. The release stated in part:

11 Separately, the U.S. Food and Drug Administration (FDA) completed its re-  
 12 inspection of the Company's Hayward manufacturing facility in connection with the  
 13 previously disclosed warning letter. In addition to the re-inspection relating to the  
 14 warning letter, the FDA conducted a general GMP inspection of the Company's  
 15 Hayward operations. At the conclusion of this additional inspection, the FDA issued  
 16 a new Form 483 with observations primarily relating to the Company's Quality  
 17 Control Laboratory. There were no repeat deficiencies or observations set forth in the  
 18 Form 483 and the observations described therein are different from the observations  
 19 raised in the warning letter. The Company has timely submitted its response to the  
 20 Form 483 to the FDA.

21 Currently, the Company has not been informed by the FDA of the impact this  
 22 latest Form 483 will have on the resolution or timing of resolving the warning letter  
 23 or whether any further regulatory action may be taken as to its manufacturing  
 24 operations. The Company has no control over the Agency's timing to review its  
 25 response or to evaluate its corrective actions. In the interim, the Company continues  
 26 to manufacture products and is working diligently to address the observations raised  
 27 by the FDA in the Form 483.

28 Dr. Hsu said ***"While we believe we have addressed the observations raised in  
 the warning letter and have instituted appropriate corrective actions, we are  
 disappointed to have received a Form 483 on these new observations.*** We believe  
 we have submitted a complete response to the Form 483 and are working diligently  
 to enhance our quality control procedures. ***We have already taken decisive action,  
 including a change in the testing laboratory leadership, as well as strengthened  
 and clarified laboratory testing standard operating procedures."***

37. On May 3, 2012, Impax filed with the SEC its Form 10-Q for its first quarter ended  
 March 31, 2012, which included the same results previously reported in the Company's May 1, 2012  
 press release. The Form 10-Q stated in part:

We have taken a number of steps to thoroughly review our quality control  
 and manufacturing systems and standards and are working with several third-party  
 experts to assist us with our review. ***This work is ongoing and we are committed to  
 improving our quality control and manufacturing practices.***



1           38.     On June 29, 2012, Impax issued a press release announcing the resignation of  
2 defendant Koch, which stated in part:

3           Impax Laboratories, Inc. (the "Company") today announced that Arthur A. Koch, the  
4 Company's Executive Vice President, Finance, and Chief Financial Officer, has  
5 informed the Company of his decision to resign from his position with the Company  
6 to pursue other opportunities. Mr. Koch will assist the Company to help ensure a  
7 smooth transition.

8           The Company also announced that Bryan M. Reasons, who currently serves  
9 as Vice President, Finance, has been appointed as Acting Chief Financial Officer and  
10 that the Company will initiate a search for a permanent successor.

11           "During the past seven years that Arthur Koch has been with us, the  
12 Company has grown tremendously, and I deeply appreciate his service to the  
13 Company," said Larry Hsu, president and CEO of Impax Laboratories. "Bryan  
14 Reasons is an able and experienced financial executive who will be the interim CFO  
15 reporting to me as we conduct an external search for a permanent CFO."

16           39.     On July 31, 2012, Impax issued a press release announcing its second quarter 2012  
17 financial results. The Company reported net income of \$18.7 million, or \$0.27 diluted EPS, for the  
18 second quarter of 2012. The release further stated in part:

19           "The positive second quarter results reflect our Zomig® tablets sales in the  
20 U.S. utilizing our expanded neurology focused brand sales force, as well as increased  
21 receipt of shipments of generic Adderall XR® from our third-party supplier which  
22 led to higher sales in the quarter," said Larry Hsu, Ph.D., president and CEO, Impax  
23 Laboratories, Inc. "We are excited that our brand sales force began promoting and  
24 sampling Zomig® tablets in the U.S. on April 1. ***This product will support the  
25 growth of our commercial organization as we prepare for the potential launch of  
26 Rytary™, our first internally developed brand product for Parkinson's Disease.***"

27           "The U.S. Food and Drug Administration (FDA) recently completed a  
28 preapproval inspection for Rytary™ and an undisclosed generic product at our  
Taiwan facility and there were no Form 483 observations. We continue to work at  
resolving the recent observation made by the FDA in Hayward and have been  
notified that a satisfactory re-inspection will be necessary to close out the warning  
letter," Dr. Hsu continued.

39.     On August 2, 2012, Impax filed with the SEC its Form 10-Q for its second quarter  
ended June 30, 2012, which included the same financial results previously reported in the  
Company's July 31, 2012 press release. The Form 10-Q stated in part:

          In June 2011, we received a warning letter from the FDA related to an on-site  
FDA inspection of our Hayward, California manufacturing facility conducted  
between December 13, 2010 and January 21, 2011. In the warning letter, the FDA  
cited deviations from current Good Manufacturing Practices (cGMP), which are  
extensive regulations governing manufacturing processes, stability testing, record

1 keeping and quality standards. In summary, the FDA observations set forth in the  
 2 warning letter related to sampling and testing of in-process materials and drug  
 3 products, production record review, and our process for investigating the failure of  
 4 certain manufacturing batches (or portions of batches) to meet specifications. The  
 5 FDA observations do not place restrictions on our ability to manufacture and ship our  
 6 products.

7 From late June 2011 through the end of 2011, we filed our response and  
 8 subsequent updates with the FDA and have continued to cooperate with the FDA to  
 9 resolve the FDA observations. In December 2011, we received an acknowledgement  
 10 letter from the FDA stating that it had received a complete response from us to the  
 11 warning letter. During the quarter ended March 31, 2012, the FDA completed a re-  
 12 inspection of our Hayward manufacturing facility in connection with the warning  
 13 letter and in addition, a general GMP inspection. As a result of the general GMP  
 14 inspection of our Hayward operations, the FDA issued a Form 483, with observations  
 15 primarily relating to our Quality Control Laboratory. We have been notified by the  
 16 FDA that a satisfactory re-inspection of our Hayward manufacturing facility is  
 17 required to close out the warning letter and such re-inspection by the FDA has not  
 18 occurred to date.

19 We have taken a number of steps to thoroughly review our quality control  
 20 and manufacturing systems and standards and are working with several third-party  
 21 experts to assist us with our review. ***This work is ongoing and we are committed to  
 22 improving our quality control and manufacturing practices.***

23 41. On October 2, 2012, Impax reached its Class Period high of \$27.02 per share.

24 42. On October 12, 2012, Impax issued a press release announcing that the FDA had  
 25 extended the Prescription Drug User Fee Act ("PDUFA") date for review of the New Drug  
 26 Application ("NDA") for Rytary from October 21, 2012 to January 21, 2013.

27 43. On October 30, 2012, Impax issued a press release announcing its third quarter 2012  
 28 financial results. The Company reported net income of \$20.0 million, or \$0.29 diluted EPS, for the  
 third quarter of 2012. The release stated in part:

29 "Our U.S. promotional efforts of Zomig® exceeded our expectations in the  
 30 third quarter and support our brand commercial organization as we continue to  
 31 prepare for the potential launch of Rytary™," said Larry Hsu, Ph.D., president and  
 32 CEO, Impax Laboratories, Inc. "The success of our brand business is an important  
 33 element to the future growth of the Company."

34 "A few weeks ago, the U.S. Food and Drug Administration (FDA) notified us  
 35 that Rytary's™ New Drug Application review date would be extended three months  
 36 to January 21, 2013. We continue to have dialogue with the FDA on both this  
 37 application and the resolution of the Hayward warning letter. We expect that upon  
 38 the resolution of the warning letter, we should begin to see approvals for generic  
 products in backlog and will look to commercialize these opportunities assuming the  
 market dynamics remain attractive. In the meantime, we continue to explore  
 investment opportunities that can deliver growth and progress the Company towards  
 its long term generic and brand division goals," Dr. Hsu concluded.

44. On November 2, 2012, Impax filed with the SEC its Form 10-Q for its third quarter ended September 30, 2012, which included the same financial results previously reported in the Company's October 30, 2012 press release. The Form 10-Q stated in part:

In June 2011, we received a warning letter from the FDA related to an on-site FDA inspection of our Hayward, California manufacturing facility conducted between December 13, 2010 and January 21, 2011. In the warning letter, the FDA cited deviations from current Good Manufacturing Practices (cGMP), which are extensive regulations governing manufacturing processes, stability testing, record keeping and quality standards. In summary, the FDA observations set forth in the warning letter related to sampling and testing of in-process materials and drug products, production record review, and our process for investigating the failure of certain manufacturing batches (or portions of batches) to meet specifications.

From late June 2011 through the end of 2011, we filed our response and subsequent updates with the FDA and have continued to cooperate with the FDA to resolve the FDA observations. In December 2011, we received an acknowledgement letter from the FDA stating that it had received a complete response from us to the warning letter. During the quarter ended March 31, 2012, the FDA completed a re-inspection of our Hayward manufacturing facility in connection with the warning letter and in addition, a general GMP inspection. As a result of the general GMP inspection of our Hayward operations, the FDA issued a Form 483, with observations primarily relating to our Quality Control Laboratory. We have been notified by the FDA that a satisfactory re-inspection of our Hayward manufacturing facility is required to close out the warning letter and such re-inspection by the FDA has not occurred to date. The FDA observations do not place restrictions on our ability to manufacture and ship our products.

We have taken a number of steps to thoroughly review our quality control and manufacturing systems and standards and are working with several third-party experts to assist us with our review. ***This work is ongoing and we are committed to improving our quality control and manufacturing practices.***

45. On December 13, 2012, Impax issued a press release announcing the appointment of defendant Reasons as CFO, which stated in part:

Impax Laboratories, Inc. announced today that Bryan M. Reasons has been appointed senior vice president and chief financial officer (CFO). Mr. Reasons, 45, joined Impax Laboratories in January 2012 as vice president, Finance, and has served as acting CFO since June 2012.

"Following a nationwide search, Bryan Reasons was selected as the best candidate to fill the CFO role," said Larry Hsu, Ph.D., president and CEO, Impax Laboratories. "He has a breadth of knowledge across accounting and finance, combined with extensive merger and acquisition experience within the pharmaceutical industry. In less than two years, we have significantly transformed Impax's leadership team across a number of functions as we focus on executing our growth strategy."



46. On January 21, 2013, Impax issued a press release announcing that it had failed to win approval for its drug Rytary, as the FDA was requiring a satisfactory re-inspection of the Company's Hayward facility as a result of the May 2011 warning letter before the Company's NDA could be approved given the facility's involvement in the development and manufacturing of Rytary.

The release provided in part:

Impax Pharmaceuticals, a division of Impax Laboratories, Inc., announced today that the U.S. Food and Drug Administration (FDA) issued a complete response letter regarding the New Drug Application (NDA) for RYTARY™ (IPX066), an extended-release capsule formulation of carbidopa-levodopa, a potential treatment for the symptomatic treatment of Parkinson's disease currently under review in the United States.

The complete response letter indicates that the FDA requires a satisfactory re-inspection of the company's Hayward facility as a result of the warning letter issued in May 2011 before the company's NDA may be approved due to the facility's involvement in the development of RYTARY, and supportive manufacturing and distribution activities. During the assessment of the NDA, the company withdrew the Hayward site as an alternative site of commercial production at launch.

"We will work with the FDA on the appropriate next steps for the RYTARY application," said Larry Hsu, Ph.D., president and CEO, Impax Laboratories, Inc. "We remain committed to resolving the warning letter and bringing this new treatment option to patients who are suffering from Parkinson's disease."

A complete response letter is issued by the FDA's Center for Drug Evaluation and Research when the review cycle for a drug is complete and the application is not yet ready for approval.

47. On February 25, 2013, Impax issued a press release announcing its fourth quarter and full year 2012 financial results. The Company reported net income of \$4.8 million, or \$0.07 diluted EPS, for the fourth quarter of 2012. Additionally, the Company reported net income of \$55.9 million, or \$0.82 diluted EPS, for the full year of 2012. The release stated in part:

"While our adjusted full year 2012 financial results improved over last year, it was still a challenging year for Impax. We faced a few obstacles on two of our key objectives for 2012 - successfully resolving the warning letter at our Hayward facility and obtaining approval of our first internally developed branded product candidate RYTARY™," said Larry Hsu, Ph.D., president and CEO, Impax Laboratories, Inc. "The resolution of the quality issues in Hayward continues to be a top priority throughout the company."

\* \* \*

1 Dr. Hsu continued, "These obstacles, however, are not preventing us from  
2 continuing to invest in developing future generic and branded product opportunities  
3 or moving forward with our long-term growth strategy. In 2012 we made significant  
4 progress in diversifying our generics business by expanding our alternative dosage  
form portfolio from 9 products in 2011 to 33 currently marketed and pipeline  
products. We also focused on building a brand pipeline through both internal R&D  
and external business development activities."

5 "We ended 2012 with almost \$300 million in cash and short-term  
6 investments, and no debt. In addition, we expect the pre-tax receipt of approximately  
7 \$150 million from Endo Health Solutions and Shire under previously announced  
agreements. These resources combined with our strong balance sheet will help to  
support our business objectives," concluded Dr. Hsu.

8 48. On February 26, 2013, Impax filed with the SEC its Form 10-K for its fiscal year  
9 ended December 31, 2012, which included the same financial results previously reported in the  
10 Company's February 25, 2013 press release. The Form 10-K stated in part:

11 In late May 2011, we received a warning letter from the U.S. Food and Drug  
12 Administration (FDA) related to an on-site FDA inspection of our Hayward,  
13 California manufacturing facility conducted between December 13, 2010 and  
14 January 21, 2011. In the warning letter, the FDA cited deviations from current Good  
Manufacturing Practices (cGMP), which are extensive regulations governing  
15 manufacturing processes, stability testing, record keeping and quality standards. In  
summary, the FDA observations set forth in the warning letter related to sampling  
and testing of in-process materials and drug products, production record review, and  
16 our process for investigating the failure of certain manufacturing batches (or portions  
of batches) to meet specifications.

17 From late June 2011 through the end of 2011, we filed our response and  
subsequent updates with the FDA and have continued to cooperate with the FDA to  
18 resolve the FDA observations. In December 2011, we received an acknowledgement  
letter from the FDA stating that it had received a complete response from us to the  
19 warning letter. During the quarter ended March 31, 2012, the FDA completed a re-  
inspection of our Hayward manufacturing facility in connection with the warning  
20 letter and in addition, a general GMP inspection. As a result of the general GMP  
inspection of our Hayward operations, the FDA issued a Form 483, with observations  
21 primarily relating to our Quality Control Laboratory. We have been notified by the  
FDA that a satisfactory re-inspection of our Hayward manufacturing facility is  
22 required to close out the warning letter. The FDA observations do not place  
restrictions on our ability to manufacture and ship our products.

23 ***We have taken a number of steps to thoroughly review our quality control  
24 and manufacturing systems and standards and are working with several third-  
25 party experts to assist us with our review. This work is ongoing and we are  
committed to improving our quality control and manufacturing practices.*** We  
26 cannot be assured, however, that the FDA will be satisfied with our corrective  
actions and as such, we cannot be assured of when the warning letter will be closed  
out. Unless and until the warning letter is closed out, it is possible we may be subject  
27 to additional regulatory action by the FDA as a result of the current or future FDA  
observations, including, among others, monetary sanctions or penalties, product  
28 recalls or seizure, injunctions, total or partial suspension of production and/or

1 distribution, and suspension or withdrawal of regulatory approvals. Additionally, the  
2 FDA has withheld and may continue to withhold approval of pending drug  
3 applications listing our Hayward, California facility as a manufacturing location of  
4 finished dosage forms until these FDA observations are resolved. If we are unable to  
promptly correct the issues raised in the warning letter, our business, consolidated  
results of operations and consolidated financial condition could be materially  
adversely affected.

5 49. Then, on March 4, 2013, Impax announced that the FDA had completed an inspection  
6 of the Company's Hayward facility. The FDA's inspection covered three areas. First, it covered a  
7 re-inspection of the Hayward facility in connection with the May 2011 warning letter to verify the  
8 implementation of corrective actions by the Company. Second, it covered a Pre-Approval Inspection  
9 for Rytary, as analytical method validation and a portion of the stability data was generated at the  
10 Hayward facility. And third, it covered a general GMP inspection. Based on its inspection, the FDA  
11 issued a new Form 483, as it had found twelve "observations" or problems at the Hayward facility  
12 that the Company needed to correct, including three repeat manufacturing problems that had not  
13 been corrected since prior inspections. The Company further indicated that due to the manufacturing  
14 deficiencies, it did not expect to be able to launch Rytary or a generic version of Concerta until 2014.

15  
16 50. Additionally on March 4, 2013, Impax filed a Form 8-K with the SEC providing a  
17 redacted version of the Form 483.  
18

19 51. On this news, Impax's stock plummeted \$5.20 per share to close at \$14.80 per share  
20 on March 5, 2013, a one-day decline of 26% on high volume.

21 52. The true facts, which were known by the defendants but concealed from the investing  
22 public during the Class Period, were as follows:

23 (a) The Company failed to maintain proper quality control and manufacturing  
24 practices at its Hayward facility in violation of cGMP.

25 (b) The Company failed to take proper remedial actions to correct quality control  
26 issues previously identified by the FDA in prior inspections at the Hayward facility.  
27  
28

1 (c) The extent of the adverse impact the manufacturing deficiencies at the  
2 Hayward facility could have on the Company's ability to successfully launch its new drug Rytary.

3 (d) Based upon the above, defendants lacked a reasonable basis for their positive  
4 statements about the Company or its outlook, including statements about its ability to launch Rytary  
5 or generic Concerta in 2013.

6 53. As a result of defendants' false statements, Impax stock traded at artificially inflated  
7 levels during the Class Period. However, after the above revelations seeped into the market, the  
8 Company's shares were hammered by massive sales, sending them down 45% from their Class  
9 Period high.

### 10 **LOSS CAUSATION**

11 54. During the Class Period, as detailed herein, the defendants made false and misleading  
12 statements and engaged in a scheme to deceive the market and a course of conduct that artificially  
13 inflated the price of Impax common stock and operated as a fraud or deceit on Class Period  
14 purchasers of Impax common stock by misrepresenting the Company's business and prospects.  
15 Later, when the defendants' prior misrepresentations and fraudulent conduct became apparent to the  
16 market, the price of Impax common stock fell precipitously, as the prior artificial inflation came out  
17 of the price over time. As a result of their purchases of Impax common stock during the Class  
18 Period, plaintiff and other members of the Class suffered economic loss, *i.e.*, damages, under the  
19 federal securities laws.  
20

### 21 **NO SAFE HARBOR**

22 55. Impax's verbal "Safe Harbor" warnings accompanying its oral forward-looking  
23 statements ("FLS") issued during the Class Period were ineffective to shield those statements from  
24 liability.  
25

26 56. The defendants are also liable for any false or misleading FLS pleaded because, at the  
27 time each FLS was made, the speaker knew the FLS was false or misleading and the FLS was  
28 authorized and/or approved by an executive officer of Impax who knew that the FLS was false.

None of the historic or present tense statements made by defendants were assumptions underlying or relating to any plan, projection or statement of future economic performance, as they were not stated to be such assumptions underlying or relating to any projection or statement of future economic performance when made, nor were any of the projections or forecasts made by defendants expressly related to or stated to be dependent on those historic or present tense statements when made.

### CLASS ACTION ALLEGATIONS

57. Plaintiff brings this action as a class action pursuant to Rule 23 of the Federal Rules of Civil Procedure on behalf of all persons who purchased or otherwise acquired Impax common stock during the Class Period (the "Class"). Excluded from the Class are defendants and their families, the officers and directors of the Company, at all relevant times, members of their immediate families and their legal representatives, heirs, successors or assigns and any entity in which defendants have or had a controlling interest.

58. The members of the Class are so numerous that joinder of all members is impracticable. The disposition of their claims in a class action will provide substantial benefits to the parties and the Court. Impax has over 68.4 million shares of stock outstanding, owned by hundreds if not thousands of persons.

59. There is a well-defined community of interest in the questions of law and fact involved in this case. Questions of law and fact common to the members of the Class which predominate over questions which may affect individual Class members include:

- (a) whether the 1934 Act was violated by defendants;
- (b) whether defendants omitted and/or misrepresented material facts;
- (c) whether defendants' statements omitted material facts necessary to make the statements made, in light of the circumstances under which they were made, not misleading;

(d) whether defendants knew or deliberately disregarded that their statements were false and misleading;

(e) whether the price of Impax common stock was artificially inflated; and

(f) the extent of damage sustained by Class members and the appropriate measure of damages.

60. Plaintiff's claims are typical of those of the Class because plaintiff and the Class sustained damages from defendants' wrongful conduct.

61. Plaintiff will adequately protect the interests of the Class and has retained counsel who are experienced in class action securities litigation. Plaintiff has no interests which conflict with those of the Class.

62. A class action is superior to other available methods for the fair and efficient adjudication of this controversy.

## COUNT I

### **For Violation of §10(b) of the 1934 Act and Rule 10b-5 Against All Defendants**

63. Plaintiff incorporates ¶¶1-62 by reference.

64. During the Class Period, defendants disseminated or approved the false statements specified above, which they knew or deliberately disregarded were misleading in that they contained misrepresentations and failed to disclose material facts necessary in order to make the statements made, in light of the circumstances under which they were made, not misleading.

65. Defendants violated §10(b) of the 1934 Act and Rule 10b-5 in that they:

(a) employed devices, schemes and artifices to defraud;

(b) made untrue statements of material facts or omitted to state material facts necessary in order to make the statements made, in light of the circumstances under which they were made, not misleading; or

(c) engaged in acts, practices and a course of business that operated as a fraud or deceit upon plaintiff and others similarly situated in connection with their purchases of Impax common stock during the Class Period.

66. Plaintiff and the Class have suffered damages in that, in reliance on the integrity of the market, they paid artificially inflated prices for Impax common stock. Plaintiff and the Class would not have purchased Impax common stock at the prices they paid, or at all, if they had been aware that the market price had been artificially and falsely inflated by defendants' misleading statements.

## COUNT II

### For Violation of §20(a) of the 1934 Act Against All Defendants

67. Plaintiff incorporates ¶¶1-66 by reference.

68. The Individual Defendants acted as controlling persons of Impax within the meaning of §20(a) of the 1934 Act. By virtue of their positions with the Company, and ownership of Impax stock, the Individual Defendants had the power and authority to cause Impax to engage in the wrongful conduct complained of herein. Impax controlled the Individual Defendants and all of its employees. By reason of such conduct, defendants are liable pursuant to §20(a) of the 1934 Act.

## PRAYER FOR RELIEF

WHEREFORE, plaintiff prays for judgment as follows:

A. Determining that this action is a proper class action, designating plaintiff as Lead Plaintiff and certifying plaintiff as a class representative under Rule 23 of the Federal Rules of Civil Procedure and plaintiff's counsel as Lead Counsel;

B. Awarding plaintiff and the members of the Class damages, including interest;

C. Awarding plaintiff's reasonable costs and attorneys' fees; and

1 D. Awarding such equitable/injunctive or other relief as the Court may deem just and  
2 proper.

3 **JURY DEMAND**

4 Plaintiff demands a trial by jury.

5 DATED: March 7, 2013

ROBBINS GELLER RUDMAN  
& DOWD LLP  
SHAWN A. WILLIAMS

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SHAWN A. WILLIAMS

10 Post Montgomery Center  
11 One Montgomery Street, Suite 1800  
12 San Francisco, CA 94104  
Telephone: 415/288-4545  
415/288-4534 (fax)

13 ROBBINS GELLER RUDMAN  
14 DOWD LLP  
15 DARREN J. ROBBINS  
16 DAVID C. WALTON  
17 CATHERINE J. KOWALEWSKI  
655 West Broadway, Suite 1900  
San Diego, CA 92101-3301  
Telephone: 619/231-1058  
619/231-7423 (fax)

18 ADEMI & O'REILLY, LLP  
19 GURI ADEMI  
20 SHPETIM ADEMI  
3620 East Layton Avenue  
Cudahy, WI 53110  
Telephone: 414/482-8000  
414/482-8001 (fax)

21 Attorneys for Plaintiff

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